

**REMARKS**

Upon entry of the foregoing amendment, claims 5 and 8-12 are pending in the application, with claims 5 and 8 being the independent claims. Claim 5 is sought to be amended. Claims 9-12 are sought to be added. Claims 1-4, 6 and 7 are sought to be cancelled by the present amendment without prejudice to or disclaimer of the subject matter therein.

Claim 5 has been amended to clarify Applicant's invention. Specifically, claim 5 has been amended to insert the term "diabetic" immediately prior to, and the phrase "with sulfonylurea secondary failure" immediately after, the term "mammal." Support for these changes can be found in the specification as filed, e.g., at page 53, lines 10-16, and claim 8 as originally filed.

Support for the addition of new claims 9-12 can be found in the specification as filed, e.g., at page 3, lines 2-7, and in claims 2 and 3 as originally filed.

These changes are believed to introduce no new matter, and their entry is respectfully requested. Reconsideration of this application is also respectfully requested.

**I. Rejection Under 35 USC § 112, Second Paragraph**

The Examiner rejects claims 4 and 7 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. (Office Action, at page 2, lines 6-10.)

Claims 4 and 7 have been cancelled, thereby rendering the rejection moot. Accordingly, Applicant believes that the rejection of claims 4 and 7 under 35 U.S.C. § 112, second paragraph, has been overcome and requests that the Examiner withdraw this rejection.

**II. Rejection Under 35 USC § 101**

The Examiner rejects claims 4 and 7 under 35 U.S.C. § 101 on the basis that the claimed recitation of a use, without setting forth any steps involved in the process, allegedly results in an improper definition of a process. (Office Action, at page 2, lines 21-23.)

As indicated above, Claims 4 and 7 have been cancelled, rendering the rejection moot. Accordingly, Applicant believes that the rejection of claims 4 and 7 under 35 U.S.C. § 101 has been overcome and requests that the Examiner withdraw this rejection.

### **III. Rejection Under 35 USC § 102**

The Examiner rejects claims 1-8 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ahrén *et al.*, *Diabetes Care* 25:869-875 (May 2002) ("Ahrén"). (Office Action, at page 3, lines 10-11.) Applicant respectfully traverses this rejection.

Specifically, the Examiner contends that Ahrén teaches that the DPP-IV (dipeptidyl peptidase IV) inhibitor NVP DPP728 is used to effectively treat type II diabetes in humans, and that GLP-1 is an incretin that causes release of insulin from beta cells and is rapidly degraded by DPP-IV. (Office Action, at page 3, lines 15-19.) The Examiner argues that if the DPP-IV inhibitor was used to treat type 2 diabetes, "it would inherently treat diabetes with sulfonylurea failure from sulfonylurea compounds and from fast acting insulin [secretagogues] since it would still inhibit DPP-IV and prevent the degradation of GLP-1 hormones." (Office Action, at page 3, lines 19-22.)

Claims 1-4, 6 and 7 have been cancelled, rendering the rejection moot with respect to these claims.

Claims 5 and 8-12, as currently presented, recite a method of treating diabetes with sulfonylurea secondary failure, or a method of promoting insulin secretion, in a diabetic patient with sulfonylurea secondary failure. These claims specifically recite that the subject is a diabetic mammal or a diabetic patient with sulfonylurea secondary failure.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, when the reference is silent about the asserted inherent characteristic, an additional reference or additional evidence may be presented to fill the gap, but the reference or evidence must make

clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *See Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). *See also* Manual of Patent Examining Procedure (MPEP), 8<sup>th</sup> Ed., § 2131.01, pp. 2100-67 to 2100-69 (August 2007).

Applicant respectfully submits that Ahrén does not disclose, either expressly or inherently, administration of the DPP-IV inhibitor to a diabetic patient with sulfonylurea secondary failure (as opposed to a diabetic patient) for treating diabetes with sulfonylurea secondary failure or for promoting secretion of insulin in a diabetic patient with sulfonylurea secondary failure. Ahrén is silent as to whether any of the patients in the disclosed study were diabetic patients with sulfonylurea secondary failure, and no additional reference or evidence has been presented to make clear that the diabetic subjects in the study disclosed in Ahrén were necessarily patients that had experienced sulfonylurea secondary failure, and that this would be so recognized by persons of skill in the art. Thus, because Ahrén does not disclose, either expressly or inherently, all the limitations of claims 5 and 8-12, it cannot anticipate these claims.

Applicant believes that the rejection of claims 1-8 under 35 U.S.C. § 102(b) has been overcome. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

#### **IV. Rejection Under 35 USC § 103**

The Examiner rejects claims 1-8 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ahrén *et al.*, *Eur. J. Pharmacol.* 404:239-245 (2000) ("Ahrén 2000") in view of Nauck *et al.*, *Diabetes Care* 21:1925-1931 (1998) ("Nauck"). (Office Action, at page 4, lines 11-12.) Applicant respectfully traverses this rejection.

Specifically, the Examiner contends that it would have been obvious to use the methods and the inhibitor of DPP-IV of Ahrén 2000 to treat diabetes with sulfonylurea secondary failure

since the compound increased levels of GLP-1, and would therefore stimulate insulin secretion in patients with diabetes with sulfonylurea secondary function. (Office Action, at page 5, lines 3-6.)

Claims 1-4, 6 and 7 have been cancelled, rendering the rejection moot with respect to these claims. With respect to claims 5 and 8-12, Applicant respectfully submits the following comments.

As admitted by the Examiner, Ahrén 2000 does not teach that the disclosed DPP-IV inhibitor (valine-pyrrolidide) can be used to treat diabetes with sulfonylurea secondary failure. (See Office Action, at page 4, lines 20-21.)

Nauck appears to disclose that intravenous administration of exogenous synthetic GLP-1 can lower plasma glucose levels in a diabetic patient with sulfonylurea secondary failure. However, Nauck does not teach that endogenous levels of GLP-1 increase in response to inhibition of DPP-IV in a diabetic patient with sulfonylurea secondary failure, or that any increase in endogenous GLP-1 in such patients, if it did occur, would be effective in lowering plasma glucose levels of the diabetic patient with sulfonylurea secondary failure.

Thus, Applicant respectfully submits that in view of Ahrén 2000 and Nauck, there would have been no reason for one of skill in the art to arrive at Applicant's claimed methods of treating diabetes with sulfonylurea secondary failure or of promoting insulin secretion in a diabetic patient with sulfonylurea secondary failure. Thus, Applicant submits that, at the time of the invention, the methods as currently claimed would not have been obvious in light of Ahrén 2000 and Nauck.

Applicant believes that the rejection of claims 1-8 under 35 U.S.C. § 103 has been overcome. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

**CONCLUSION**

Based on the foregoing remarks, Applicant respectfully requests that the Examiner reconsider all rejections and that they be withdrawn. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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